

OCT 29 1999



UNITED STATES DEPARTMENT OF COMMERCE
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#15

Mollie M. Yang
Merck & Co., Inc.
PO Box 2000
RAHWAY NJ 07065-0907

Re: Patent Term Extension
Application for
U.S. Patent No. 4,427,663

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,427,663, which claims the animal drug product IVOMEC®EPRINEX™ Pour-On for Beef and Dairy Cattle, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,255 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,255 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 8, 1998 (63 Fed. Reg. 36922). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,475) + 17 \\ &= 1,255 \text{ days}\end{aligned}$$

Since the regulatory review period began June 22, 1990, after the patent issue date (January 24, 1984), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year limit of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,427,663
Granted:	January 24, 1984
Original Expiration Date ¹ :	March 16, 2002
Applicant:	Helmut H. Mrozik

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Merck & Co., Inc.

Title: 4"-Keto-And 4'-Amino-4"-Deoxy Avermectin
Compounds and Substituted Amino Derivatives
Thereof

Product Trade Name: IVOMEC®EPRINEX™ Pour-On for Beef and
Dairy Cattle (eprinomectin)

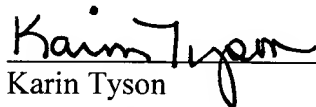
Term Extended: 1,255 days

Expiration Date of Extension: August 22, 2005

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents By FAX: (703) 308-6916
Box Patent Ext. Attn: Special Program Law Office
Washington, D.C. 20231

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff CDEV
Food and Drug Administration
1451 Rockville Pike HFD-7
Rockville, MD 20852

RE: IVOMEC®EPRINEX™
Pour-On for Beef and Dairy Cattle

FDA Docket No.: 97E-0308